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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,244	06/04/1999	DARYL W. HOCHMAN	48000.1002U	3962

20601 7590 05/20/2003

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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/20/2003

2-1

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/326,244

Applicant(s)

HOCHMAN, DARYL W.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 11, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9, 11, 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election of species of pathological tissues or cells in Paper No. 20 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

An action on the merits of pending claims 2-9, 11, 17, and 19 as they read on the elected species, follows. All rejections and objections not reiterated below are hereby withdrawn.

Drawings

New corrected drawings are required in this application as set forth on Form PTO 948, mailed to applicant with paper #8 (the office action of 10/2/00. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5, 7, 9, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by O'BRIEN et al. (Journal of Dental Research (1989), vol. 68 (2), pages 157-158).

O'BRIEN teaches a method of identifying an optical contrast enhancing agent for increasing the sensitivity of optical detection of a biological material in an organ (tooth) by comparing optical data acquired from teeth (multiple samples) after exposure to a test agent and a candidate (dye) to optical data from controls. O'BRIEN uses his comparison data to determine if his dye is useful for distinguishing pathological tissue; i.e. caries lesions (p. 157), therefore claims 4, 5, 17 and 19 are anticipated. O'BREIN teaches that his dye is detected by absorption (p. 158), therefore claim 9 is anticipated. O'BRIEN teaches that his teeth are exposed to a physiological challenge/toxin (acid) prior to optical detection of lesions (p. 157), thereby anticipating claims 3 and 7.

Claims 2, 6, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by MASHBERG (US 4,321,251).

MASHBERG (US 4,321,251) teaches a method wherein a viable intact organism is exposed to a dye (optical contrast enhancing agent), the results compared to comparison data, and the dye identified as one useful for distinguishing malignant tissue (see Table I). As malignant tissue is one type of "pathological" tissue, claims 11 and 17 are anticipated. MASHBERG's comparison data is empirically derived (Table 1), therefore claim 6 is anticipated. MASHBERG's dye is applied to multiple sites/lesions in the mouths of his intact organisms, therefore MASHBERG inherently collects data from multiple spatial locations in his samples, and claim 2 is anticipated.

Claims 3, 7, 8, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by HANSEN et al. (Diabetes Research (Feb. 1989) volume 10 (2), pages 53-57).

HANSEN teaches a method wherein cells in tissue culture from different rats (i.e. different populations of cells in *in vitro* systems) are exposed to dizithone (a dye), the results compared to comparison data (various responses), and the dye identified as one useful for identifying pancreatic islets, particularly in methods of diagnosing insulin disorders (abstract), thereby anticipating claims 8 and 17. HANSEN teaches exposing his cells to stimulatory glucose concentrations (a biological agent/drug), therefore claims 3 and 7 are anticipated.

Conclusion

Claims 2-9, 11, 17, and 19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

MA Moran